

EXHIBIT C

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master file no. 2:12-md-02327 MDL
THIS DOCUMENT RELATES TO PLAINTIFFS: DIANE KROPF Case No. 2:12-cv-01202	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE MDL No. 2327

**RULE 26 CASE SPECIFIC EXPERT REPORT OF
RICARDO R. GONZALEZ, M.D.**

I am Dr. Ricardo R. Gonzalez. The medical opinions rendered in this report represent my opinions, all held to a reasonable degree of medical certainty, and are based on a reasonable medical probability and scientifically reliable evidence. In forming my opinions, I have also relied on the general opinions of the experts disclosed in this litigation. I reserve the right to supplement my opinions in this matter as new information becomes available.

I. QUALIFICATIONS, BACKGROUND, AND EXPERIENCE

I am currently a Clinical Assistant Professor of Urology at the Baylor College of Medicine in Houston, Texas. In addition, I am the Medical Director for both the Center for Voiding Dysfunction and Center for Clinical Research. I received my MD degree in 1999 from the Stanford University School of Medicine. Following graduation from medical school, I completed a residency in Urology and a fellowship in Female Urology, Neurology, and Voiding Dysfunction at the Weill Cornell Medical Center. I became board certified in Urology in 2008, and additional board certification in Female Pelvic Medicine and Reconstructive Surgery in 2013. I have published articles and given lectures on the topics of repair of urinary incontinence. I am clinical faculty and instruct medical students and residents for Baylor College of Medicine in Urology and voiding dysfunction. As part of my continuing medical education, I have attended training seminars provided by the American Urological Association, Society for Urodynamics, Female Pelvic Medicine, and Urogenital Reconstruction, and manufacturers including American Medical Systems and Boston Scientific. I have served as a cadaver lab preceptor for American Medical Systems and Boston Scientific and am currently involved in the FDA 522 studies related to a

single-incision sling system (Boston Scientific) and biological grafts for prolapse (Boston Scientific). Throughout my career, I have performed hundreds of pelvic floor surgical procedures, including abdominal sacrocolpopexy, uterosacral suspensions, sacrospinous ligament fixations, native tissue repairs, biological graft repairs and synthetic mesh repairs. In addition, I have performed over 80 surgeries dealing with complications related to synthetic mesh slings, including the removal of numerous sling devices. Recently, I have personally examined ten women who had received the ObTape sling and have had complications.

A copy of my CV is attached as Exhibit "A", a list of my testimony for the last four years and Fee Schedule is attached as Exhibit "B." The documents for which I have read and relied on for this report are contained in Exhibit "C" as well as those documents cited throughout this Report and my IME Report is attached as Exhibit "D".

II. MATERIALS REVIEWED AND APPLICABLE METHODOLOGY

In preparation for this report, I reviewed Ms. Diane Kropf's medical records, her deposition testimony, and Plaintiff Fact Sheet ("PFS"), along with the deposition testimony of Drs. Patricia Murray and Charles Beamon. Additionally, I conducted an examination of Ms. Kropf, which was performed in a manner consistent with my standard clinical practices. I have also conducted an extensive review of relevant medical literature and a number of internal documents from mesh manufacturers as they apply to this case. The materials reviewed are more fully set forth in the attached materials reliance list.

In my practice, I determine the cause of the patient's condition based upon an interview with the patient, an examination, a review of her medical records, if available, and discussion of her prior medical history. I then complete a differential diagnosis to determine the cause of a specific injury. Differential Diagnosis is a universally accepted methodology in the United States whereby a physician "rules in" a potential cause and then by elimination, the physician "rules out" the least likely cause. I eliminate potential causes until I reach a cause that cannot be ruled out. I performed this differential diagnosis in arriving at my opinions in this case after reviewing the medical history provided, performing my examination of Ms. Kropf, reviewing her medical history, both verbal and as supplied in the medical records provided, and reviewing her test results, including laboratory tests.

All of my opinions in this case have been reached and are offered to a reasonable degree of medical certainty.

Pelvic Organ Prolapse/Ethicon Prolift

Pelvic organ prolapse (POP) is a condition in which one or more female pelvic organs (bladder, rectum, intestines, and/or uterus) to drop or protrude into the vagina as a result of weakened pelvic muscles. This occurs as a result of aging, multiple childbirths, genetic predisposition, frequent heavy lifting, obesity, or constipation.

Treatment plans are based on patient specific factors and the risks and benefits that apply to each unique patient. In some patients, POP is mild and asymptotic and doesn't require specific therapy; in these situations, the safest treatment option is observation with periodic reevaluations. Additional options include behavioral therapy, pelvic floor exercises, and pessary use. Surgical intervention is used as a last resort for patients with more severe POP who have failed conservative measures. Traditional or native tissue POP repairs involve stitching together the patient's own vaginal, or native tissue to support the vagina and repair POP. This can be done by a transvaginal approach through the vagina or an abdominal approach. In both approaches, stitches are placed under direct vision, the surgeon can see where the stitch is going. Allowing direct visualization reduces the risk of injury to surrounding tissues and pelvic organs, in contrast to the blind insertion of the Prolift System.

The Prolift System

The Prolift System was heavily marketed by Ethicon as a way to increase the durability of POP repair making it superior to traditional non-mesh repairs. This superiority was based upon a misperceived higher failure rate and exaggerated recurrence rates of traditional repairs. Ethicon launched the Prolift System in 2005, it marketed and sold The Prolift System in the United States for over three years prior to obtaining FDA clearance in May of 2008.

The Prolift System comes in three different options; each option has a self-contained kit and procedure. Each kit is similar except for the shape of the mesh and varying surgical components for insertion and retrieval: (1) GyneCare Prolift Anterior Pelvic Floor Repair System – for repair of cystocele (bladder prolapse); (2) GyneCare Prolift Posterior Pelvic Floor Repair System – for repair of rectocele (rectal prolapse); (3) GyneCare Prolift Total Pelvic Floor Repair System – for repair of cystocele, rectocele, and vaginal vault prolapse. While Ethicon's brochures characterize the procedure as "minimally invasive" there is no doubt that the system's implantation constitutes major invasive surgery. The mesh contained in each Prolift system is composed of non-absorbable knitted filaments of polypropylene which resemble their Prolene mesh. Prolift is reported to have a reduced polypropylene diameter fiber which is marketed to be more flexible. The Prolift is identical in its construction to Ethicon's Gynemesh PS and Prolene Soft Mesh. The proposed clinical use for Prolene Soft Mesh is for hernia repair and fascial defect repair.

Complications

Inadequate tissue integration due to inadequate porosity and pore size can result in the development of a rigid scar plate, potentially leading to erosion, nerve entrapment, pain syndromes, dyspareunia, and loss of elasticity and mesh contraction.

Fibrotic bridging and scar plate formation prevent tissue in-growth because there isn't space for the tissue to grow into the mesh as it is intended to do. Mesh wrinkling or curling can also prevent tissue in-growth and may lead to fibrotic bridging.

Vaginal wound healing

Granulation, extrusion, and erosion involve poor vaginal wound healing and represent significant complications with possible permanent symptoms such as pain and infections. Internal Ethicon documents and studies show a post-operative erosion and/or extrusion exposure rate of 13.7% with a 14.1% rate in the US. Over half of these required surgical repair.¹

Complications such as mesh "granulation" or "wound granulation" are associated with poor vaginal healing and possible mesh infection. Symptoms may include, but are not limited to, foul smelling or bloody vaginal discharge, pelvic pain, pelvic discomfort, dyspareunia, and vaginal wound infection.

"Extrusion" or "erosion" are sometimes used interchangeably, but they do differ. It is generally accepted that mesh "extrusion" indicates that the significant inflammation caused by the mesh impairs vaginal wound healing to such a degree as to cause the mesh to be exposed through the vaginal wall. Symptoms of extrusion may include, but are not limited to, pelvic pain, pelvic discomfort, dyspareunia, vaginal wound infection, and foul smelling and bloody vaginal discharge.

Mesh "erosion" differs in that the synthetic mesh has *worn* through the wall of the urethra, or the bladder, rectal, or intestinal walls and can be serious and possibly life-threatening. Symptoms of erosion may include, but are not limited to, pelvic pain, vaginal pain, pain with urination, bladder infection, foul smelling or bloody vaginal discharge, dyspareunia, vaginal wound infections, fever, sepsis, and pelvic organ dysfunction.² Since granulation, extrusion, and erosion likely represent the same problem with poor vaginal healing, they all represent significant complications with possible permanent symptoms such as pain and infections.

Ethicon's internal documents confirmed that they were aware that mesh contracture caused a foreign body response. Despite this knowledge, Ethicon mislead physicians and patients by claiming the Prolift mesh did not noticeably impair wound healing.

Continuous Organ Injury

Ethicon's Device Design Safety Assessment (DDSA) states that the expected risk of vital organ perforation with the Prolift procedure is "*rare*" (1 in 100,000 maximum). However, injury to adjacent pelvic organs have been reported to occur in as many as 3-6.6% of patients implanted with the Prolift System. This is because the female pelvis is packed with multiple anatomic structures in very close spatial proximity and all Prolift trocars are passed blindly. This can result

¹ ETH.MESH.00081035; ETH.MESH.00081083; ETH.MESH.00080954; ETH.MESH.00081006; ETH-01121 – 01122; ETH.MESH.00081000- 00081001.

² Haylen et al., An International Urogynecological Association (IUGA) International Continence Society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) and grafts in female pelvic floor surgery. *Int Urogynecol J* 2011; 22:3-15.

in serious injury to the bladder, pelvic nerves, ureter, and major pelvic blood vessels even with the highest skilled surgeon.

Mesh contraction

Polypropylene surgical mesh is known to contract and shrink when placed in the body. The reported incidence of contraction ranges from 11-20% and can result in infection, chronic vaginal and pelvic pain, vaginal shortening and narrowing, infection, and vaginal fibrosis. Despite knowing of the risk of contraction and the negative consequences associated with contraction, Ethicon failed to provide adequate warning of either.

Foreign body reaction

There is a consensus, based on an abundance of literature, that synthetic meshes with larger pore size, lighter weight, and less surface area, better structural stability and elasticity will have fewer complications and better results. Of all the mesh characteristics, porosity, pore size and stability under load are the most important.³ If the mesh does not allow for incorporation, fibrotic bridging can occur which leads to formation of a rigid scar plate. This can lead to complications such as erosion, extrusion, exposure, contraction, pain, nerve entrapment, dyspareunia, and organ dysfunction.⁴ Ethicon failed to warn of the above listed adverse events.

Degradation

Numerous studies have shown that polypropylene is not biologically inert and is subject to oxidation and degradation. Literature and Ethicon's own studies illustrate that polypropylene meshes degrade, oxidize, crack, and peel in human tissue.⁵ Not only did Ethicon fail to warn physicians and patients that Prolift mesh would degrade in human tissue, but it intentionally misled physicians and patients by asserting that the Prolift system was "not subject to degradation or weakening by action of tissue enzymes."⁶

Pain Syndromes

Chronic pelvic, vaginal, and buttock pain can occur following the implantation of the Prolift system due to several reasons. The blind insertion during implantation can cause injury to the pelvic muscles and anatomy which can result in chronic pain and inflammation. Mesh contraction,

³ Klinge U, Klosterhalfen B, Birkenhauer V: Impact of polymer pore size on the interface scar formation in a rat model. *J. Surgical Research* 103, 208-214 (2002).

⁴ ETH.MESH.00869977 – 00870098; ETH.MESH.02589033 – 02589079; ETH-80645 – 80651; Robinson Deposition 3-13, p 120; Hinoul Deposition 4-5, pl65-l; Robinson Deposition 3-13, pl29-130; Kirkemo Deposition 4-18, p138.

⁵ Liebert T, Chartoff R, Costgrove S. Subcutaneous Implants of Polypropylene Filaments. *J.Biomed. Mater. Res.* 1976; 10:939-951, Williams D. Review Biodegradation of surgical polymers. *Journal of Materials Science.* 1982; 17:1233-1246, Celine Mary, Yves Marois, Martin W. King, Gaetan Laroche, Yvan Douville, Louisette Martin, Robert Guidoin, Comparison of the In Vivo Behaviour of Polyvinylidene Fluoride and Polypropylene Sutures Used in Vascular Surgery, *ASAIO Journal*, 44 (1998) 199-206, Wood, et al. Materials Characterization and histological analysis of explanted polypropylene, PTFE, and PET hernia meshes from an individual patient. *J Mater Sci: Mater med* (2013) 24:1113-1122, DEPO.ETH.MESH.00000367, ETH.MESH.09557798, ETH.MESH.15144988, ETH.MESH.00874032, ETH.MESH.07192929, B. Klosterhalfen presentation "What can we learn from explanted meshes?", Depositions of Thomas Barbolt and Daniel Burkley and exhibits thereto

⁶ ETH-01777; ETH.MESH.00570955; ETH.MESH.02589066-02589068;

curling, and roping create sharp edges that can result in pain. Nerve trauma, nerve entrapment, and disruption due to excessive scarring and scar plate formation can also cause chronic pain syndromes. Ethicon was aware of these complications but failed to include them in Prolift IFUs.

Sexual dysfunction

Sexual dysfunction can be the result of several factors such as contraction, vaginal shrinkage and/or shortening, scarring, or any other mesh related injuries. Depending on the severity of these factors, outcomes can range from mild discomfort during sexual relations to loss of sexual functioning. The progressive nature of mesh contraction can lead to delayed onset of sexual dysfunction. Internal documents show that Ethicon was aware of this complication and failed to warn physicians and patients.⁷

Stress Urinary Incontinence/TVT

Stress Urinary Incontinence is the involuntary leakage of urine during physical activity that increases abdominal pressure.

Nonsurgical treatments include: (1) pelvic floor exercise, also known as Kegel exercises which improve pelvic floor muscle strength; (2) a removable device known as a pessary which is inserted into the vagina to support the bladder neck; (3) transurethral bulking agents which are injections applied around the urethra; (4) behavior modification such as avoiding activities that trigger leaking; (5) Urinary seals which are adhesive foam pads placed over the urethral opening to prevent leakage; (6) a Urethral insert which is a thin flexible solid tube placed into the urethra to block urine leakage; (7) a bladder neck support device which is a flexible ring with two ridges, once the ring is inserted into the vagina, the ridges press against the vaginal walls supporting the urethra.

Surgical treatments include (1) the Burch Colposuspension, the goal of the Burch procedure is to suspend and stabilize the urethra. This procedure can be done laparoscopically but is not ideal for patients with type III SUI as no hypermobility exists to correct. (2) Pubovaginal sling procedures which have an excellent overall success rate and are a durable cure. A band of autologous, allograft, xenograft, or synthetic material is placed directly under the bladder neck which acts as physical support to prevent descent during physical activity. (3) Midurethral synthetic sling procedure which was theorized to correct incontinence by recreating the midurethral support of the pubourethral ligament and by creating a midurethral hammock for support during stress events.

Polypropylene mesh (Prolene) contained in the TVT

Several published studies have found a causal relationship between the design of the mesh and incidents of post-operative complications. The polypropylene mesh contained in the TVT has many well-known characteristics that make it unsuitable for permanent implantation in the human

⁷ ETH-80645 – 80651; Walji Deposition 3-8, p398-399; Walji Deposition 3-8, p365-366; Gauld Deposition Rough 4-26, p200; Hinoul Deposition 4-5, p200; ETH.MESH.02017152 2007 Expert Meeting; ETH.MESH.00870466: 2006 Expert meeting; ETH.MESH.01220871 email from Kammerer re: D'Art Conversation with Prof. Jacquetin; ETH.MESH.05448541: Email from Susanne Landgrebe re shrinkage review; ETH-18761: email from Kelly Brown re: Proposal for work with CBAT; ETH.MESH.00130117: Email from Ophelie Berthier re ICS Prolift Abstracts; ETH-80318

vaginal floor, a use for which it was intended. Characteristics making it unsuitable include but aren't limited to: mesh degradation; contraction/shrinkage of encapsulated mesh; deformation of the mesh, fraying, roping, and curling; loss of pore size or pore collapse due to tension; chronic foreign body reactions; infections and bio-films; and fibrotic bridging leading to the formation of scar plates and mesh encapsulation.

It is my opinion, to a reasonable degree of medical certainty, that the polypropylene mesh in the TVT causes a multitude of injuries as a result of the above and other mesh inadequacies. These injuries include but are not limited to: (1) worsening incontinence; (2) chronic and debilitating pelvic pain; (3) worsening incontinence; (4) recurrence; (5) chronic dyspareunia; (6) wound infection and wound healing problems; (7) mesh rejection; (8) ureters injury; (9) formation of pelvic abscesses; (10) the need for additional surgical procedures; (11) pelvic nerve injury; (12) urinary dysfunction; and (13) defecatory dysfunction. Additional injuries include sexual dysfunction and vaginal scarring. In addition to the above injuries, an individual would also have the possibility of suffering multiple erosions that occur their lifetime. Accordingly, Ethicon's TVT mesh is not suitable for the application it was intended for – a permanent prosthetic implant for women suffering from stress urinary incontinence.

Chronic Foreign Body Reaction

Most women who undergo permanent mesh implantation, will have their implant for decades. Bernd Klosterhalfen, a pathology expert for Ethicon informed the company that the reaction between mesh and human tissue can continue for up to 20 years.⁸

The human body has a host defense response to foreign objects placed inside the body. The body's white blood cells are dispatched to attack the foreign object; if the foreign object is not destroyed, the initial inflammatory phase is followed by the chronic inflammatory phase. When permanent surgical mesh is placed inside the body, this foreign body response reacts to the implant. Because polypropylene is a non-absorbable synthetic, it causes a foreign body reaction in the pelvic tissue so there is no way to safely implant the product into this tissue without an increased risk of serious complications. Ethicon's own medical directors have testified that the chronic foreign body reaction from the body's response to mesh can cause a severe inflammatory reaction that can cause chronic pain, erosion, nerve entrapment, dyspareunia and the need for additional surgeries.⁹ One of Ethicon's lead engineers indicated that the foreign body reaction is not transitory; it can decrease over time to a minimum level but it doesn't ever go away.¹⁰ Yet, Ethicon failed to place such a warning in its IFU or communicate this warning to physicians.

It is my opinion to a reasonable degree of medical certainty that polypropylene mesh in the TVT creates a foreign body reaction that can lead to severe complications in patients. Complications may include: 1) the possibility of multiple erosions that can occur throughout one's lifetime; 2) worsening incontinence chronic and debilitating pelvic pain, 3) recurrence, 4) chronic dyspareunia, 5) wound infection, 6) mesh rejection, 7) urinary and defecatory dysfunction, 8) sexual

⁸ ETH.MESH.00870466 (June 6, 2006 Ethicon Expert Meeting Meshes for Pelvic Floor Repair, Norderstedt).

⁹ Hinoul Dep. (4/5/12) 99:09-25; (4/6/12) 518:14-520:20; (6/26/13) 175:1-176:17; 184:18-22; 328:10-24; Owens Dep. (9/12/2012) 98:11-99:07.

¹⁰ ETH.MESH.00211259.

dysfunction, 9) vaginal scarring, 10) injury to ureters, 11) wound healing problems, and 12) possible pelvic abscess formation.

Pore Size and Fibrotic Bridging

Inadequate tissue integration caused by inadequate porosity and pore size can reasonably be expected to result in the development of a rigid scar plate, potentially leading to erosion, nerve entrapment, pain syndromes, dyspareunia, and loss of elasticity and mesh contraction. Small mesh pores that cause fibrotic bridging can turn the mesh into a solid sheet of scar tissue. Fibrotic bridging and scar plate formation prevent tissue in-growth because there isn't space for the tissue to grow into the mesh as it is intended to do. This can cause complications including mesh shrinkage and/or contraction, mesh erosion, nerve entrapment, chronic pain, and dyspareunia.

Ethicon failed to inform physicians and patients that its mesh product was susceptible to fibrotic bridging or that this bridging could lead to the above complications.

Mesh Contraction/Shrinking

Polypropylene surgical mesh is known to contract and shrink when placed in the body. This shrinkage relates to the wound healing process and takes place after the surgical trauma of a foreign body being implanted in the vaginal and pelvic tissue. This contraction/shrinkage is related to the size of the pores and the weight of the mesh. Heavy weight mesh with small pores leads to fibrotic bridging which, as mentioned above, leads to the formation of scar plates. Ethicon knew that heavier weight mesh led to greater contraction/shrinkage. Mesh has been known to contract/shrink 30-50% since 1998.¹¹ Ethicon specifically, knew about the degree of shrinkage by 1998 when its own consultants, Uwe Klinge and Bernd Klosterhalfen noted in published works that polypropylene mesh shrinks 30-50%.¹² Ethicon knew that its mesh would contract/shrink and failed to warn physicians about this possibility or of the painful complications that can result from shrinkage/contracture.

Polypropylene mesh contracts in all patients, and in some patients, this leads to painful complications such as worsening incontinence, chronic dyspareunia, nerve entrapment, wound infection, rejection of the mesh, urinary and defecatory dysfunction, formation of pelvic abscess, chronic pain, recurrence of prolapse, vaginal wall stiffness and scarring, vaginal anatomic distortion, and erosion. When this occurs the mesh cannot be safely and effectively revised or removed.

It is my professional opinion to a reasonable degree of medical certainty that polypropylene mesh used in TVT would shrink/contract and lead to painful complications in women who were implanted with the device.

¹¹ Klinge, U, *Shrinking of Polypropelen Mesh in Vivo: An Experimental Study in Dogs*, Eur J Surg 1998, 164:965-969.

¹² Klinge U, Klosterhalfen B, Muller M, Ottinger A, Schumpelick V. Shrinking of Polypropylene Mesh in vivo: An Experimental Study in Dogs. Eur J Surg. 1998; 164; 965-969

Prolene Mesh in TVT Degrades over Time

Ethicon first developed sheets of Prolene mesh for the use by surgeons in treating hernias. In claiming the safety and efficacy of their pelvic mesh product to regulatory bodies, Ethicon relied on information and science from the mesh used for hernia repair. The products placement in the vagina creates problems not seen with abdominal placement for hernia treatment. The structural complexities of the vagina along with chemicals found in the vagina and surrounding tissue present unique problems. Numerous studies have shown that polypropylene is not biologically inert and is subject to oxidation and degradation. Studies suggest oxidation of mesh occurs because of the polypropylene and the conditions where it is placed.¹³ This oxidation causes the mesh to become brittle, crack and break apart, to degrade.¹⁴ Studies have shown polypropylene to be chemically reactive; flaking and fissuring leads to degradation and releases toxic compounds into the pelvic tissue. This degradation and release of toxic compounds enhance inflammatory and fibrotic reactions in the tissue of the pelvic floor. Ethicon's own studies illustrate that polypropylene mesh can oxidize, crack, and peel in humans.¹⁵

Polypropylene is vulnerable to highly oxidized substances such as peroxide. It is known to physicians that vaginal tissues are ready sources for peroxide and that the hydrogen peroxide produced by the vaginal species lactobacillus is important in controlling vaginal micro-flora. Additionally, microbial agents such as Candida that can be found inside the normal and abnormal flora of the vagina and pelvic infections such as Bacillus and Pseudomonas, can be a source of biological degradation of polypropylene products.

Significant amount of medical literature concludes polypropylene mesh incites a specific immune response, creating within the vagina a foreign body reaction that directly causes mesh degradation, mesh contraction, fibrosis, vaginal narrowing. It is my professional opinion to a reasonable degree of medical certainty that the mesh used in TVT degrades and that the effect of this degradation in female tissue can lead to greater foreign body reaction, excessive scarring, and enhanced inflammatory response. Ethicon failed to inform physicians about the potential for degradation and the numerous complications that could follow this degradation.

Fraying, Particle Loss, Roping and Curling, Deformation and Loss of Pore Size

Because of the way Ethicon designed TVT mesh, particles separate when stress is put on the mesh. This separation is known as fraying and was described by an Ethicon engineer as a defect due to Ethicon's method of cutting mesh with a blade. This engineer stated that if the cutting method was changed to laser cutting or ultrasonic cutting, they would limit the fraying defect

¹³ Costello C., et al., "Characterization of Heavyweight and Lightweight Polypropylene Prosthetic Mesh Explants from a Single Patient," Surgical Innovation, 2007, 143:168- 176).

¹⁴ Id.

¹⁵ Liebert T, Chartoff R, Costgrove S. Subcutaneous Implants of Polypropylene Filaments. J.Biomed. Mater. Res. 1976; 10:939-951, Williams D. Review Biodegradation of surgical polymers. Journal of Materials Science. 1982; 17:1233-1246, Celine Mary, Yves Marois, Martin W. King, Gactan Laroche, Yvan Douville, Louisette Martin, Robert Guidoin, Comparison of the In Vivo Behaviour of Polyvinylidene Fluoride and Polypropylene Sutures Used in Vascular Surgery, ASAIO Journal, 44 (1998) 199-206, Wood, et al. Materials Characterization and histological analysis of explanted polypropylene, PTFE, and PET hernia meshes from an individual patient. J Mater Sci: Mater med (2013) 24:1113-1122, DEPO.ETH.MESH.00000367, ETH.MESH.09557798, ETH.MESH.15144988, ETH.MESH.00874032, ETH.MESH.07192929, B. Klosterhalfen presentation "What can we learn from explanted meshes?", Depositions of Thomas Barbolt and Daniel Burkley and exhibits thereto

significantly.¹⁶ In 2001, Dr. Alex Wang, who is known to be one of the most experienced TVT users in the world, reported problems related to the mesh fraying.¹⁷ By November 2003, Ethicon's medical director, Dr. Martin Weisberg reported 58 complaints of fraying since the product had been introduced only three years earlier in 2000. In a memo dated November 18, 2003, Dr. Weisberg reported observing that the mesh elongates in places, narrows in places, and that the mesh stretching increases the possibility of fraying.¹⁸ A few months later, on February 27, 2004, Ethicon received complaints from surgeons that brittle mesh and particles were falling into the operating field. Despite his observations and the number of fraying complaints, Dr. Weisberg concluded that fraying did not affect the safety or efficacy of the device; therefore, Ethicon determined not to pursue corrective action.¹⁹ By November 2004, one of the top 3 complaints regarding the mesh product included mesh fraying, yet Ethicon maintained it did not affect product safety.²⁰ The complaints about fraying and particle loss continued until by 2010, complaints indicated that pieces of mesh were being found in unopen packages of mesh. Ethicon continued to maintain its products safety.

Additionally, mechanically cut mesh has been shown to curl, rope, and become deformed under tension. Mesh curling and roping increase the risks of complications because they prevent adequate tissue in-growth and may lead to fibrotic bridging and chronic inflammatory events, which increase the risk of complications. Ethicon knew of the hazards of curling, roping, fraying, and inadequate pore size and that these hazards could lead to erosion, recurrence, and pain.²¹

Infections/Bio-films

The vagina is not sterile and can never be completely sterilized. In TVT, the weave of the mesh produces small interstices that allow bacteria to enter. The bacteria secretes an encasing polysaccharide slime (biofilm) which serves to shield it from the host defenses designed to eliminate them. Consequences of the biofilm increase the foreign body reaction and can result in chronic infections and chronic inflammation as well as erosion, and mesh and scar contracture. The biofilm protects the bacteria surrounding the mesh from the body's host defense response which inhibits the body's ability to fight off infection within the mesh.

When the mesh degrades, polypropylene particles separate from the surface of the mesh fiber, the resulting increase of the surface area provides greater area for the bacteria to adhere to the mesh. This increases the polypropylene's release of toxic compounds which increases the inflammatory reaction. The flaking and cracking that occur while the mesh degrades provides a safe harbor for infectious bacteria. Mesh exposure and erosion cause further exposure to bacteria; these bacteria will adhere to the mesh surface and colonize. It is my opinion to a reasonable degree of medical certainty that TVT mesh is susceptible to biofilm formation and is thus not suitable for its intended application. Ethicon failed to warn physicians and patients that biofilm could form on the mesh and lead to erosion, recurrent, late infections and necessitate removal of the product.

¹⁶ ETH.MESH.01813975 at 2 (Ex. 3160/3587).

¹⁷ ETH.MESH.03905472 (6/4/01 Emails from Wang, A. re TVT Recommendation for Ethicon Study of Fraying/Particle Loss).

¹⁸ ETH.MESH.00541379 (11/18/03 Memo from Weisberg re Mesh Fraying for TVT Devices Inadequate Testing).

¹⁹ ETH.MESH.00541379 (11/18/03 Memo from Weisberg re Mesh Fraying for TVT Devices Inadequate Testing).

²⁰ ETH.MESH.01813975 (Ex. T-3160 / T-3587).

²¹ ETH.MESH.01218019.

III. CASE-SPECIFIC OPINION

A. Pertinent Medical History

Mrs. Kropf is a 71 year old G3P3003 female. Her surgical history is remarkable for fibromyalgia, arthritis, and asthma. She has had back pain due to a sacral fracture and multiple issues for years. She has had disc spacers from L4-S1 without change in back pain; however, her back pain has nothing to do with the pain she has experienced since the implant of her vaginal mesh.

In May 2008, Mrs. Kropf presented to Dr. Murray with a second degree cystocele, second degree uterine prolapse, and vaginal mucosal atrophy. Less than one year later, in March 2009, Mrs. Kropf reported problems with urinary incontinence.

On April 5, 2010, Mrs. Kropf had a third degree cystocele and second degree rectocele, and underwent a vaginal hysterectomy, bilateral salpingo-oophorectomy, anterior vaginal wall repair using Gynemesh Prolift, placement of a TVT-O, and an enterocele repair. This procedure was performed by Dr. Patricia Murray without any reported complications.

On July 3, 2012, Mrs. Kropf presented to the Gynecology Associates of Fredericksburg with urinary frequency, dysuria and atrophic vaginitis. A pelvic exam performed on March 28, 2013 confirmed exposed mesh on the left anterior vaginal wall. At this time, estrogen vaginal cream was prescribed for the erosion; however, Ms. Kropf still presented with exposed mesh on September 24, 2013.

Due to exposed mesh, Mrs. Kropf continued to experience persistent pelvic pain and urinary symptoms. As a result, Dr. Charles Beamon operated on Mrs. Kropf on November 11, 2014. During this procedure, Dr. Beamon removed a piece of mesh from the left side of Mrs. Kropf's vaginal floor.

B. Independent Medical Examination

I conducted a medical examination on Ms. Kropf on November 16, 2015 and she described the symptoms of vaginal and abdominal pain, dyspareunia, and complications secondary to mesh erosion. Abdominal examination: the liver and spleen appear to be normal, abdomen is obese and distended. Abdominal scars are well-healed. No abdominal masses or tenderness noted. No CVA tenderness of the left or right kidneys.

No cystocele is present. A grade 2 rectocele is present. No splinting to empty bowels. Cervix and Uterus were surgically absent. She has a vaginal mesh extrusion of the left proximal Prolift arm and cuff. A 5mm x 10mm area is exposed and friable; this bleeds easily. The lateral attachment into the pelvic side wall is moderately tender to palpation. There is less banding on the right, but it is also compatible with likely mesh contracture; no right side banding has extruded. She has significant atrophy around her introitus, especially posteriorly.

Subsequent to my medical examination and thorough review of Ms. Kropf's medical records, I came to the following conclusions to a reasonable degree of certainty: vaginal and abdominal pain, dyspareunia, and complications of multiple erosions secondary to the placement of the Prolift.

It is my recommendation that Ms. Kropf would benefit from: excision of the extruded mesh and tight mesh contractures of the proximal Prolift arms. I also recommend that she comply with the topical estradiol therapy that was prescribed, as it will likely improve her atrophy, which will help her heal better from any planned mesh revision.

C. The Ethicon Products Caused Ms. Kropf's Injuries

I am familiar with the medical complications that are generally associated with pelvic repair surgery. I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by transvaginal mesh and sling implants. Among the most common complications associated with polypropylene mesh implants that I am personally familiar with are scar bands or scar plates in the vagina, vaginal shortening, vaginal stenosis, erosion of mesh into tissues or organs, nerve entrapment as a result of mesh scarring and fibrotic bridging, pelvic pain, scarring in the vagina, scarring in the pelvic floor, permanent or chronic dyspareunia, stress urinary incontinence, urge incontinence, urinary retention, constipation or fecal incontinence, encapsulation of mesh (mesh covered in thick scar tissue), chronic inflammation of the tissues or organs, and deformed, curled, folded, wrinkled, degraded and fragmented mesh after removal. Medical literature published also reports on these types of complications.²²

In my practice, I determine the cause of the patient's condition based upon an interview with the patient, an examination, a review of her medical records, if available, and discussion of her prior medical history. I then complete a differential diagnosis to determine the cause of a specific injury. Differential Diagnosis is a universally accepted methodology in the United States by practicing physicians in my field, whereby a physician "rules in" a potential cause and then by elimination, the physician "rules out" the least likely cause.²³ I then eliminate potential causes until I reach a cause that cannot be ruled out. I have performed this differential diagnosis after reviewing the medical history provided, performing my examination of Ms. Kropf, reviewing her medical history, both verbal and as supplied in the medical records provided, and reviewing her test results, including laboratory tests. I performed this differential diagnosis to rule out potential likely causes of her injuries. I also ruled out potential comorbidities and potential causes of the injuries and symptoms Ms. Kropf complained of.

My review of Ms. Kropf's medical records revealed that the mesh implantation procedures were completed within the standard of care. In reviewing Ms. Kropf's medical records, I found no deviation from the standard of care provided by Drs. Murray or Beamon.

²² Shah, et. al., *Mesh complications in female pelvic floor repair surgery and their management: A systematic review*. Indian J Urol. 2012 Apr; 28(2):129-53; Barski D, et al., *Systematic review and classification of complications after anterior, posterior, apical, and total vaginal mesh implantation for prolapse repair*, SurgTechnol Int. 2014, 24:217-24.

²³The American Heritage (2007)

In my judgment, to a reasonable degree of medical and scientific certainty, the injuries suffered by Ms. Kropf, including vaginal and abdominal pain, dyspareunia, and complications due to multiple erosions of the mesh, are a direct result of shrinking, contraction, and scarring of the mesh products and their inadequate design as described above, including the foreign body reaction they elicit.

D. Ethicon Failed to Warn Ms. Kropf and Her Implanting Surgeon of Known Serious Risks of Complications Resulting from Prolift and TVT

I have reviewed the Information for Use for both the Prolift and the TVT, and it is clear that Ethicon failed to provide the proper warnings associated with its products. The risks and adverse reactions that Ethicon knew and failed to report include, but are not limited to, Ethicon's inadequate testing of the product with no long-term studies, inadequate guidance for providing the proper tension, insufficient data to support this use of Prolene mesh, insufficient statements that its mesh was associated with only a slight and transient inflammatory response when Ethicon knew the inflammatory response was significant in some patients, insufficient warnings related to mesh degradation, incomplete warnings related to dyspareunia for sexually active women, and insufficient warnings about the contraction of the mesh that can cause pain among other complications.

I have reviewed the entirety of Dr. Murray's testimony, which informs my opinion of the types of information that Ethicon failed to warn her of. Specifically, Ms. Kropf's implanting physician, Dr. Murray, testified that, if she knew the Prolift mesh did not remain soft and pliable, and the mesh would become rigid and hard in a number of patients, it would have impacted her decision to use the Prolift product in Ms. Kropf.²⁴ She further testified that if she had known the implant of the Prolift would cause a chronic inflammatory reaction in more than 5% of the patients, she would not have used the Prolift.²⁵ Dr. Murray also testified that if she had known that mesh exposure were considered common by Ethicon employees, it would have impacted her decision to use the products.²⁶

Furthermore, Ethicon failed to warn Dr. Murray that the Prolift should not be used on sexually active patients and that a hysterectomy should not be performed at the same time as implanting the Prolift, and Dr. Murray testified that if she had been informed of these issues, she would not have used the Prolift.²⁷

These risks, adverse reactions, and warnings, as well as the clinical consequences, should have been clearly stated in the IFU so that Dr. Murray would be fully informed, and so Ms. Kropf could have been properly informed.

²⁴ Deposition of Dr. Murray, 112:13-22.

²⁵ Id. at 118:23 – 119:20.

²⁶ Id. at 128:6-21.

²⁷ Id. at 129:15 – 130:19; 133:8-134:3.

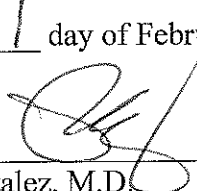
CONCLUSION

To a reasonable degree of medical certainty, based on Ms. Kropf's medical records, the depositions of her and her physicians, and my examinations of Ms. Kropf, it is my opinion that Ms. Kropf's injuries, including vaginal and abdominal pain, dyspareunia, and complications due to multiple erosions of the mesh secondary to the placement of Gynecare Prolift and TVT-O were caused by the shrinking, contraction, and scarring of the mesh and the defective design of the products as previously described, including the foreign body reaction they elicit.

My opinions in this case are based on my background, training, and experience as a clinician, as well as the materials I have reviewed in this case. Additionally, in forming my opinions, I have relied on the general opinions disclosed in this litigation, as referenced throughout. My opinions regarding the cause of the injuries suffered by Ms. Kropf are expressed to a reasonable degree of medical certainty and are based on reasonable medical probability and scientifically reliable evidence.

I have conducted my own review of the pertinent medical literature independently verifying the opinions reviewed and expressed herein. I reserve the right to supplement my opinions in this matter as necessary.

Dated this 1 day of February, 2016.



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RICARDO R. GONZÁLEZ, M.D.

Education	Stanford University School of Medicine,	M.D.	1999
	Stanford, CA		
	Occidental College, (Honors in Psychobiology)	A.B.	1994
	Los Angeles, CA		
	University of North Texas	1990 - 1992	
	Denton, TX		

Professional Specialties (Board Certification)

American Board of Urology, Diplomate	2008
Female Pelvic Medicine and Reconstructive surgery (FPMRS)	2013
American Board of Urology and American College of Obstetrics and Gynecology	

Honors

America's Top Urologists List,	
Consumers' Research Council of America	2007- 2013
Patient's Choice Award	2009- 2013
Texas Super Doctors, Rising Star Award	2012- 2013
Top Doctors	2013
<i>Texas Monthly</i> award based on peer review	
Doctor's Choice Award, Top Physicians in Houston	2009
One of ten urologists chosen by peers by Health & Fitness Magazine	
Ferdinand Valentine Fellow for Research in Urology,	
New York Academy of Medicine	2005 - 2006
Kidney and Urology Foundation of America	
Research Fellowship	2005 - 2006
American Urological Association, Gerald P. Murphy Scholar	2005 & 2006
Cornell Alumni Council Distinguished House Staff Award, Urology	
New York Presbyterian Hospital-Cornell (biennial award)	2004
Jack Lapides Prize in Neurourology and Urodynamics,	
Honorable Mention	2004
Ferdinand Valentine Essay Contest, New York Academy of Medicine	
Laboratory Research Honorable Mention	2004

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	Basic Science Research Award, Research Insights into Interstitial Cystitis Symposium of the NIDDK	2003
	Andlinger Fellow, American-Austrian Foundation	2003
	Graduation Speaker, Stanford School of Medicine	1999
	Medical Scholar, Stanford School of Medicine	1994 - 1995
	Magna Cum Laude, Occidental College	1994
	Phi Beta Kappa	1994
	M.B. Scott Scholar (Academic Merit), Occidental College	1992 - 1994
	Dean's List, U. of North Texas and Occidental College	1992 - 1994
Clinical Interests	Voiding dysfunction, female pelvic medicine and reconstructive surgery, andrology, neurourology, urodynamics, and laser prostatectomy.	
Clinical Appointments	<u>The Methodist Hospital and St. Luke's Episcopal Hospital, Houston, TX</u>	
	Attending Urologist	
	Houston Metro Urology	2006-present
	Medical Director, Center for Voiding Dysfunction	
	Medical Director, Center for Clinical Research	
	<u>Baylor College of Medicine, Houston, TX</u>	
	Clinical Assistant Professor of Urology	2006-present
	<u>The New York Presbyterian Hospital – Weill Cornell Medical Center</u>	
	Resident: Department of General Surgery	1999 - 2001
	Resident: James Buchanan Brady Department of Urology	2001 - 2004
	Chief Resident: Brady Department of Urology	2004 - 2005
	Fellow: Neurourology, Female Urology, Voiding Dysfunction	2005 - 2006
	Clinical Instructor, Assistant Attending in Urology	2005 - 2006
Research Grants	Principal Investigator: Modulating Bladder Neuroinflammation: Investigating Potential Diagnostics and Therapeutics for Interstitial Cystitis. Ferdinand Valentine Research Fellowship, New York Academy of Medicine New York, NY.	
		2005 - 2006
	Principal Investigator: The Role of Estrogen in Modulating Bladder Neuroinflammation and Permeability: Potential Rationale for Increasing LUTS in Aging Women.	
	Kidney and Urology Foundation of America Research Fellowship.	
	New York, NY	2005 - 2006
Research Experience	<u>Resident then Fellow, Department of Urology, Weill Cornell Medical Center</u>	
	New York, NY	2000 - 2006
	PI: Alexis E. Te M.D., Steven A. Kaplan M.D. and David Staskin M.D.	
	Institute for Bladder and Prostate Health, Weill Cornell Medical Center.	
	Subjects: Modulating the neuroplasticity observed in bladder inflammation, and investigating new potential therapies for interstitial cystitis. Using high-power lasers for the treatment of BPH. Minimally invasive approaches for pelvic floor reconstruction of prolapse.	

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Research Assistant, Mayo Vaccine Research Group, Mayo Clinic
 Rochester, MN Summers of 1995 and 1996
 PI: Gregory A. Poland, M.D., Founder and Director of the Mayo Vaccine Research Group, and Associate Director of the General Clinical Research Center, Mayo Clinic and Foundation.
 Subject: Investigating the measles vaccination status, measles antibody seroprevalence, and immunogenetic typing of Hispanic migrant farmworkers.

Research Assistant, Division of Neurosurgery, Stanford University
 Stanford, CA 1994 - 1995
 PI: Gary K. Steinberg, M.D., Ph.D., Chair of the Division of Neurosurgery, Stanford University School of Medicine
 Subject: Elucidating the metabolic mechanisms of hypothermic neuroprotection in a model of focal ischemia in the rat brain.

Honors Thesis Research, Department of Psychobiology, Occidental College
 Los Angeles, CA 1993 - 1994
 PI: Nancy K. Dess, Ph.D., Professor of Psychobiology, Occidental College.
 Subject: Establishing the differences in the development of activity-based anorexia in two lines of rats differing in general metabolic efficiency.

Richter Fellow, Universidad Autónoma de Madrid, Hospital Del Niño Jesús
 Madrid, Spain Summer 1993
 PI: Jesús Argente, M.D., Ph.D., Head, Division of Pediatric Endocrinology and Metabolism, Hospital Del Niño Jesús.
 Subject: The effectiveness of orally-administered Growth Hormone (GH) Releasing Peptide-2 at stimulating GH release in children.

Publications

Journal Articles

Hueber PA, Liberman D, Tal BZ, Woo H, Hai M, Te AE, Lee R, Rutman M, **González RR**, Barber N, Al-Hathal N, Al-Aaoud T, Trinh QD, Zorn ZC. 180W vs 120W lithium triborate photoselective vaporization of the prostate for benign prostatic hyperplasia: a global, multi-center comparative analysis of peri-operative treatment parameters. *Urology*, in press 2013 URL-D-13-00280R1

Hollander AB, **González RR**. Evaluation and management of urgency and urge urinary incontinence in men. *Current Bladder Dysfunction Reports*, Volume 7, Number 3 (2012), 230-234.

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Saini R, **González RR**, Te AE. Chronic pelvic pain syndrome and overactive bladder: the inflammatory link. *Curr Urol Rep*. 2008 Jul;9(4):314-9.

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Kaplan SA, **González RR**. Phosphodiesterase type 5 inhibitors for the treatment of male lower urinary tract symptoms. *Rev Urol* Spring 2007; 9(2): 73-77.

Kaplan SA, **González RR**, Te AE. Combination of alfuzosin and sildenafil is superior to monotherapy in treating lower urinary tract symptoms and erectile dysfunction. *Eur Urol*. 2007 Jun; 51(6):1717-23.

González RR, Te AE. Chronic Prostatitis/Pelvic Pain Syndrome: a bladder dysfunction? *Curr Bladder Dysfunction Rep* Mar. 2007; 2(1): 55-59.

González RR. Advances in Female Urology. *The Urology Report* Winter 2007 ; 1(1): 10-15.

Lee R, Al-Ahmadie HA, Boorjian SA, **González RR**, Felix Badillo, Rueter VE, Steckel J. A case of incidental adrenocortical oncocytoma. *Nat Clin Pract Urol* Nov 2006; 3(11): 618-21.

Ng, CK, **González RR**, Te AE. Refractory overactive bladder in men: update on novel therapies. *Curr Urol Rep* Nov. 2006; 7(6): 456-61.

Lee R, **González RR**, Te AE. The evolution of photoselective vaporization prostatectomy (PVP): advancing the surgical treatment of benign prostatic hyperplasia. *World J Urol*. 2006 Sep; 24(4): 405-9.

González RR, Kaplan SA. First line BPH treatment: is there a particular patient profile for a particular treatment? *World J Urol*. 2006 Sep; 24(4): 360-6.

González RR, Kaplan SA. Tadalafil for the treatment of lower urinary tract symptoms in men with benign prostatic hyperplasia. *Expert Opin. Drug Metab. Toxicol*. 2006 Aug; 2(4): 609-17.

González RR, Te AE. Is there a role for urodynamics in chronic nonbacterial prostatitis? *Curr Urol Rep* July 2006; 7(4): 335-38.

Monoski M, **González RR**, Sandhu JS, Reddy B, Te AE. Urodynamic predictors of outcomes with photoselective laser vaporization prostatectomy in patients with benign prostatic hyperplasia and preoperative retention. *Urology* 2006; 68(2): 312-7.

Monoski M, **González RR**, Thomas A, Goldstein M. Arteriovenous malformation of the scrotum causing virtual azoospermia. *Urology* 2006; 68(1): 203.e5-6.

González RR, Te AE. The role of urodynamics in chronic nonbacterial prostatitis. *Curr Prostate Rep* April 2006; 4(1): 41-4.

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Sandhu JS, Nb CK, **González RR**, Kaplan, SA, Te AE. Photoselective laser vaporization prostatectomy in men receiving anticoagulants. *J Endourol* Dec 2005; 19(10): 1196-8.

Reddy BN, **González RR**, Te AE. The implications of cytokines in chronic prostatitis and chronic pelvic pain syndrome. *Curr Prostate Rep* Nov 2005; 3(4): 189-94.

Shelton JB, Barocas DA, Conway F, Hart K, Nelson K, Richstone L, **González RR**, Raman JD, Scherr DS. Prostate-specific antigen screening in a high-risk population: lessons from the community and how they relate to large-scale population-based studies. *Urology*. 2005 May; 65(5): 931-6.

González RR, Fong T, Belmar N, Saban M, Felsen D, Te AE. Modulating bladder neuroinflammation: RDP58, a novel anti-inflammatory peptide, reduces inflammation and nerve growth factor production in experimental cystitis. *J Urol* 2005 Feb; 173(2): 630-4.

González RR, Te AE. Chronic Prostatitis and sensory urgency: whose pain is it? *Curr Urol Rep*. 2004 Dec; 5(6): 437-41.

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Multimedia

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Book Chapters

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González RR, Lee R, Sandhu J, Te AE. Laser prostatectomy. *Atlas of the Prostate, Third Edition*. Eds. Scardino PT and Slawin KM. Philadelphia: Current Medicine, Inc.; December 2005.

Presentations

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Mercado MA, Dunkin BJ, **González RR**. Proving face, content, and construct validity for a photoselective vaporization of prostate (PVP) simulator. *Research to be presented as a podium presentation at the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) in February 2012 in Las Vegas, NV*.

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González RR. "Take Home Messages" for BPH and Male Lower Urinary Tract Symptoms. Plenary presentation at the American Urologic Association Annual Meeting in Atlanta, Georgia; May 23, 2012.

Khavari R, Sathyamoorthy K, **González R**, Fletcher S. Impaired detrusor contractility and the treatment of female stress incontinence. Presented at Society for Urodynamics, Female Pelvic Medicine, and Urogenital Reconstruction; New Orleans, LA, March 1, 2012.

González RR. Photoselective Laser Vaporization of the Prostate, Standardizing Surgical Technique. Surgical video presentation, World Congress of Endourology; Kyoto, Japan, December 2, 2011.

Goh H, Knerr M, Su L, David SG, **González RR**. Photoselective Laser Vaporization Prostatectomy Versus Transurethral Resection of the Prostate: A Cost Analysis. *J Urol* 2009 April, 181(4): 766.

González RR. Will TURP die? Representing laser prostatectomy in live debate with surgeries. Congresso Paulista de Urologia; Sao Paulo, Brazil, September 4, 2010.

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González RR. State of the art treatment for the enlarged prostate: Lithium Boride 120 W laser prostatectomy. Presented with live surgeries at the 25th Annual Meeting, Korean Andrological Society; Busan, Korea, April 3, 2008.

Sander JC, Avila D, **González RR.** Safely integrating new technology into urological practice: evaluation of a training model for Photoselective Laser Vaporization Prostatectomy (PVP). Presented at the 25th Annual Meeting, Korean Andrological Society; Busan, Korea, April 3, 2008.

González RR. Incorporating new technology into your developing practice: experience with the GreenLight HPS. Presented at American Urological Association Annual Meeting, Anaheim, CA, May 21, 2007.

González RR. Advances in the treatment of the enlarged prostate: a focus on laser prostatectomy. Presented at the Society for Urologic Nurses and Associates (SUNA) regional meeting, Houston, TX, April 18, 2007.

González RR. Photoselective Laser Vaporization Prostatectomy (PVP): Technique and Outcomes. Presented at Baylor Urology Grand Rounds, the Methodist Hospital, Houston, TX, Mar 28, 2007.

Te AE, Yang JH, **González RR**, Reddy BN, Zhou X, Madhu M, Kaplan SA. Safety and efficacy of photoselective laser vaporization of the prostate for benign prostatic hyperplasia in men over 80 years. Presented at the Western Section AUA Annual Meeting, Maui, HI, Oct 22, 2006.

Te AE, **González RR**, Reddy BN, Kaplan SA. Photoselective laser prostatectomy-vaporization incision technique for large prostates. Presented at the Western Section AUA Annual Meeting, Maui, HI, Oct 22, 2006.

Kaplan SA, **González RR**, Ogiste J, Te AE. Combination of an alpha-blocker, alfuzosin SR and a PDE-5 inhibitor, sildenafil citrate, is superior to monotherapy in treating lower urinary tract symptoms (LUTS) and sexual dysfunction. Abstract #1638 *J Urol* 2006, 175(4): 528.

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González RR, Reddy B, Chen J, Staskin DR, Te AE. Effects of short-term estrogen deprivation on experimental bladder inflammation. Abstract #189 *J Urol* 2006, 175(4): 61-2.

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González RR. Combination medical therapy for BPH. Panelist at the Society for Female Urology and Urodynamics Annual Meeting, Grand Bahamas, February 22-25, 2006.

González RR, Reddy BN, Sandhu JS, Kaplan SA, Te AE. High-power KTP photoselective laser vaporization prostatectomy: the New York Presbyterian experience. Presented at the Society for Female Urology and Urodynamics Annual Meeting, Grand Bahamas, February 22-25, 2006.

El-Hakim A, **González RR**, Beneck D, Tewari AK. Sub-detrusor, pre-seminal vesicle fascia: characterization and composition. Presented at the World Congress of Endourology, Amsterdam, Netherlands, Aug 24, 2005.

Monoski MA, Sandhu JS, **González RR**, Te AE. Urodynamic predictors of success with photoselective laser vaporization prostatectomy in patients with benign prostatic hyperplasia and preoperative retention. Abstract #1305 *J Urol* 2005, 173(4): 354.

Te AE, Sandhu JS, Reddy B, Ng CK, **González RR**, Kaplan SK. The first 200 patients treated with high-power KTP photoselective laser vaporization prostatectomy: the New York Presbyterian experience. Abstract #1561 *J Urol* 2005, 173(4): 423.

Sandhu JS, Isom-Batz G, **González RR**, Shemtov M, Te AE, Eilber K. Transurethral resection of the prostate following radiation therapy for prostate cancer. Presented at the Society for Urodynamics and Female Urology, Orlando, FL, February 24-27, 2005.

Sandhu JS, Ng CK, **González RR**, Kaplan SK, Te AE. Photoselective vaporization Prostatectomy in anticoagulated men. Presented at the World Congress of Endourology, Mumbai, India, *J Endourol.* 2004, Nov; 18 Suppl1: A3-246.

Sandhu JS, Ng CK, **González RR**, Kaplan SK, Te AE. High-power KTP photoselective laser vaporization prostatectomy in men with large prostates. Presented at the World Congress of Endourology, Mumbai, India, *J Endourol.* 2004, Nov; 18 Suppl 1: A3-246.

González RR, Belmar N, Fong T, Te AE. Modulating the bladder neuroinflammatory loop: RDP58, a novel anti-inflammatory peptide, reduces nerve growth factor production in murine models of inflammatory cystitis. Presented at the Lapides Award Ceremony AUA Annual Meeting, May 8-13, 2004.

Te AE, Sandhu JS, Ng C, **González RR**, Egan C, Kaplan SA. High-power photoselective laser vaporization prostatectomy (PVP) versus transurethral electrovaporization of the prostate (TVP) for the treatment of benign prostatic hyperplasia (BPH): a prospective comparative trial. Abstract #1527 *J Urol* 2004, 171(4): 402.

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Sandhu JS, Ng C, **González RR**, Kaplan SA, Te AE. High-power KTP photoselective laser vaporization prostatectomy in men with large prostates: The New York Presbyterian series of 64 patients. Abstract #1522. *J Urol* 2004, 171(4): 400.

González RR, Belmar N, Tesi RJ, Fong T, Te AE. RDP58, a novel anti-inflammatory peptide, inhibits inflammatory histopathology and cytokine production in a mouse model of experimental cystitis. Basic Science Research Award for podium presentation at the Research Insights into Interstitial Cystitis Symposium of the NIDDK, Oct. 30- Nov. 1, 2003; Alexandria, VA.

Iyer S, **González RR**, Zhao J, Lazarov M, Welihinda A, Buelow R, Te AE, Fong T. RDP58, a rationally designed peptide, inhibits multiple forms of pathogenic inflammation through the inhibition of p38MAPK and JNK. *Peptide Revolution: Genomics, Proteomics & Therapeutics*, podium presentation Annual Meeting of American Peptide Society, July 2003, Boston, MA.

González RR, Fong T, Felsen D, Te AE. The effect of DMSO on bladder inflammation in a murine model of acute inflammatory cystitis. Abstract #268. *J Urol* 2003, 169(4): 68-69.

González RR, Fong T, Felsen D, Te AE. RDP58 reduces bladder inflammation in a murine model of acute inflammatory cystitis. Abstract #264. *J Urol* 2003, 169(4): 69-70.

González RR, Fong T, Felsen D, Te AE. The effect of RDP58 and DMSO on inflammation in a murine model of acute inflammatory cystitis. Presented at the Society for Female Urology and Urodynamics Annual Meeting, April 26, 2003, Chicago, IL.

González RR, Coleman JA, Poppas D. Laparoscopic heminephroureterectomy in infants and children with renal duplication: a description of technique and review of outcome. Presented at the Ferdinand Valentine Essay Contest, 2002, New York, NY.

González RR, Camacho LE, Poland GE. Lessons learned in using cultural sensitivity in recruiting Hispanic migrant farmworkers and their dependents into clinical research. (Abstract) *Journal of the Association for Academic Minority Physicians* 1997; 8 (4): xvii.

González RR, Berg HZ, Ledo R, Jacobson RM, and Poland GA. Measles vaccine delivery in children of Hispanic migrant farmworkers: failure to meet the Healthy People 2000 immunization goal. Presented at the 30th National Immunization conference, April 9, 1996, Washington, D.C.

Poland GA, **González RR**, Berg H, Ledo R, Jacobson RM, Marshal J, Rogers S, and Riggs BL. Recruitment of Hispanic migrant farmworkers into

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clinical studies; lessons learned. Submitted to NIH GCRC Program to supplement grant M01-RR00585.

González RR, Maier CM, Ahern K. vB., Steinberg GK. A novel technique for regionally quantifying adenylyate levels in the rat brain. Poster presented at the Thirteenth Annual Stanford Medical Research Symposium, May 3, 1996, Palo Alto, CA.

Maier CM, Ahern K. vB., **González RR**, Steinberg GK. Effects of mild and moderate hypothermia on neurologic outcome, infarct size, and adenylyate levels following transient MCA occlusion in rats. *Society of Neuroscience Abstracts*. 1995; 22: 1030.

González RR, Dess, NK. The effectiveness of a competing-response model in developing activity-based anorexia in two lines of rats differing in "emotionality". Poster presented and abstract published in the *Proceedings of the Annual Conference of the Society for the Advancement of Chicanos and Native Americans in the Sciences*, March 1994, Chicago, IL.

Teaching And Education

Surgical Proctor and Trainer for Photoselective Laser Vaporization Prostatectomy with GreenLight from 2005 to today. Invited lectures and live surgical training including Baylor College of Medicine, University of Southern California, Kaiser Permanente Southern California and Irvine, University of California San Francisco, Stanford, University of Texas Medical Branch Galveston, Cedars Sinai, Argentina, Venezuela, Brazil, Mexico, Costa Rica, Columbia, Ecuador, Bolivia, Panama, Japan, South Korea and Taiwan.

Faculty Member, Benign Prostatic Hyperplasia (BPH) Courses, 2005- 2013 American Medical Association Continuing Medical Education Courses.

Responsible for syllabus and sessions on minimally invasive surgical options for BPH and laser safety, including lectures and laboratory.

Spanish-Language Editor [volunteer], American Urological Association's patient education web site (www.UrologyHealth.org) 2005-present
Topics include: bladder trauma, overactive bladder, enlarged prostate, and kidney stones.

Cornell Resident Panelist, American College of Graduate Medical Education (ACGME) Cornell-Columbia Outcomes Project for Systems-Based-Practice. Developed case scenarios to present at various departments' grand rounds to test the six ACGME competencies. 2004-2005

Coordinator and Presenter, Cornell-Pfizer Urology Symposium. Developed to review general urology for pharmaceutical executives and sales representatives. 2003
New York, NY. November 8, 2003.

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	Teaching Assistant, Department of Anatomy, Stanford University School of Medicine.	1995
	Teaching Assistant, Algebra II, Summer Opportunities for the Academically Ready (SOAR; Program for talented, underprivileged minorities), at the University of North Texas.	1991
Administrative Activities	Director (founding), Center for Voiding Dysfunction Houston Metro Urology	2008 - present
	Founding Member, Cornell Center for Pelvic Pain	2004 - 2006
	Chief Resident, Department of Urology	2004 - 2005
	President, Stanford Medical Students Association	1996 - 1997
	Member, Steering Committee on LCME Reaccreditation	1996 - 1997
	Member, Stanford's Council on Diversity -to restructure affirmative action program	1996 - 1997
	Recruiter, File Reviewer, and Interviewer for Stanford Medical School Office of Admissions.	1995 - 1997
	State Representative (Stanford), California Chicano Medical Student Association	1994 - 1995
Memberships	American Urological Association Society for Urodynamics and Female Pelvic Medicine and Urogenital Reconstruction International Urogynecological Association Endourological Society American Society of Reproductive Medicine American Medical Association	
Interests	Farming, spinning, and travel.	
Personal	Fluent in Spanish. Married (Marcela) with three sons Texas State License: M3237	

**Exhibit
B**

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RICARDO R. GONZALEZ, M.D.

FEE SCHEDULE

\$500 per hour for review of documents or meetings
\$6,000 per half-day deposition or trial testimony
\$10,000 per full-day deposition or trial testimony

PREVIOUS TESTIMONY

June 2012:	Quick v. Mel Dugan, et al. Alabama Retained by Lorance & Thompson Defense witness
November 2014:	White Ross v. C.R. Bard Villnave v. C.R. Bard Mueller v. C.R. Bard Mitchell v. C.R. Bard Messer v. C.R. Bard Douglas-Jones v. C.R. Bard Groover v. C.R. Bard Gruman v. C.R. Bard

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Parisi Testimony re: changes to IFU's or Prof. ED materials since new warnings/IFU's
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DEPOSITIONS

Piet Hinoul, MD, Ph.D
David Robinson, MD
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Jennifer Paine
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Sean O'Bryan
Charlotte Owens
Dr. James Hart
Bryan Lisa
Brian Kanerviko
Price St. Hilaire
Alex Gorsky
Renee Selman
Cliff Volpe

DVD's:

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PLAINTIFFS' MEDICAL RECORDS

PLAINTIFF'S DEPOSITION W/EXHIBITS

PLAINTIFF'S FACT SHEET

TREATING DOCTORS' DEPOSITION W/EXHIBITS:

Dr. Patricia Murray
Dr. Charles Beamon
Dr. Edward Gill

GENERAL EXPERT REPORTS FILED IN THE LITIGATION

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ETH-03420-03479	Prolift design & development.
ETH-03430	
ETH-03480-03530	Concept DDSA.
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ETH-03568-03578	Design failure modes effects analysis.
ETH-03579-03876	Development Completion Report.
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ETH-04022-04068	Material Specifications.
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NEW IFU

Original IFU.

Prolift Clinical Data Synopsis.

Southern Midwest Regional Meeting

06/07/08 email from St. Hilaire to Maher & Jones

Parisi Testimony re: changes to IFU's or Prof. ED materials since new warnings/IFU's

Parisi testimony re changes to IFU's or Prof ED Materials since new warnings updates.pdf

KROPF, DIANE (Date of Birth: Feb 10, 1944)

MESH PROBLEMS

Nov 16, 2015

HISTORY / PHYSICAL

PQRS DOCUMENTATION:

Date Current Medications Verified 11/16/2015. List of current medications (includes prescription, over-the-counter, herbals, vitamin/mineral/dietary [nutritional] supplements) documented by the provider, including drug name, dosage, frequency and route.

Documentation that Pneumococcal vaccine administered or previously received.

BMI Screening and Follow-Up - reported on this patient 11/16/2015. Calculated BMI below normal parameters and a follow-up plan was documented.

PQRS tobacco reported on this patient 11/16/2015.

Patient screened for tobacco use. Current non-user.

PRESENT ILLNESS: The patient is a 71 year old White female who presents today for a new patient visit. Family of patient is present in the examination room. Patient specifically stated that any discussion concerning her medical condition can be discussed with the family member(s) present: husband.

Mrs. Kropf is here for complications with vaginal mesh.

In the past, she has had 3 pregnancies and 3 vaginal deliveries. The first labor was 23 hours, the second was breach and the third had a "cord around her neck". She does not recall any forceps used or lacerations involving her rectum. She did tear "quite a bit" with the breached delivery.

She has had back pain due to a sacral fracture and multiple issues for years. She has had disc spacers from L4-S1 without change in back pain. That kind of pain has nothing to do with the type of pain that she is having since the vaginal mesh.

She reports that the bladder problems started years (about 20 years) after the vaginal deliveries.

Her urinary symptoms worsened in the late 2000's that she describes as worsening urinary frequency, urgency, and incontinence. She tried some medicines, but they did not help very much. She was "disgusted" by a vaginal bulge and wanted it corrected. She was hoping the prolapse correction would help her bladder. It did not give her pain. Urodynamics preoperatively did not show an overactive bladder nor ISD. She believes she was offered a Pessary and exercises, but she wanted her problem "fixed".

She had vaginal hysterectomy, Prolift anterior with TVT for urethral hypermobility (G3 cystocele, G2 rectocele) in April 2010. She initially was happy to not have the bulge there. Even her urinary frequency improved for a few months, then it started to get worse by 2011. She was found to have "granulation tissue" around May 2010 requiring silver nitrate treatment 6 months after. "I kept on bleeding".

In the ensuing years, she had difficulty controlling the pain after the operation and had issues with pain medications, "trying to get the pain under control".

By March 18, 2013, the mesh was exposed and found during intercourse by her husband who was having excoriations on his penis. No mesh was excised. She was started on topical estradiol vaginal 9/30/2013. In 11/11/2014, she had explantation of a left extruded vaginal mesh band due to persistent bleeding and pain. She does not feel that this helped and wonders why they did not take all of the mesh out.

She has not been sexually active since the initial vaginal mesh extrusion around March 2013. He reports penile abrasions and pain if he tries to have sex with her.

"Knowing what I know now, I would absolutely not ever have this again".

Just sitting there, she describes her pain as 0-1/10. If she gets up to walk, it is a 7/10 pain. The pain is vaginal and in her inner thighs. Her husband chimes in and feels that "they injured her pudendal nerve".

She is bothered to squat on the toilet outside of her house (does not want to sit on dirty commode), she cannot empty well and the "urine runs down my legs". She is bothered by her abdominal girth and weight gain since her mesh surgeries. She feels she cannot be active due to the pain.

She has chronic constipation. She used Miralax almost daily with improvement until stopping her regimen. She uses a suppository or Fleets for breakthrough. She can urinate every 2 hours during the day. She has nocturia 1 x without enuresis. She does wear a pad at night. She rarely uses a pad during a day. Her urination is "under control now" other than the positional issues with voiding. She wishes she did not have pain and did not urinate "all down her legs" since the mesh placements. She wishes she could some day have sex again.

ACTIVE MEDICATIONS:

Date medications last reviewed with patient: 11/16/15

Foltanx Vitamin B Complex oral tablet, # once a day

Lisinopril - 5 mg oral tablet 10 mg oral tablet, # once a day

Morphine Sulfate 15 mg oral tablet, # three times a day

Topamax 100 mg oral tablet, # once a day

TraZODone Hydrochloride 100 mg oral tablet, # once a day

ALLERGIES:

Date patient last asked about allergies: 11/16/15

Medication Allergies: NKDA

Environmental Allergies: DUST, POLLEN, TREES

PFSH: Updated - 11/16/2015

PAST MEDICAL HISTORY: Anemia, Hypertension, Allergies, Constipation, Diarrhea, GERD, Hemorrhoids, Bladder Infection, Hematuria, Menopause, Arthritis, Back Pain, Fibromyalgia, Anxiety, Chronic Fatigue Syndrome, Depression, Asthma, Bronchitis, Pneumonia

PAST SURGICAL HISTORY: Laminectomy 2004, Cholecystectomy 2007, Cystoscopy 2012, Hysterectomy 2010, Unilateral Oophorectomy 2010, Facial Surgery 1985, Nasal Surgery 1965, Tonsil Surgery (T and A), Back Surgery 2004, foot surgery

FAMILY HISTORY:

Arthritis - Father, Mother

Depression- Mother

High Blood Pressure - Mother, Sister, Son

Kidney Disease - Sister

Tuberculosis - Grandmother

SOCIAL HISTORY:

Marital Status: Married

Daily Alcohol Consumption: occasional-social

Does not smoke or use any tobacco products.

Caffeine Use: low

Travel History: There is a history of travel to Mexico.

REVIEW OF SYSTEMS: Updated - 11/16/2015

Constitutional: Fatigue.

Gastrointestinal: Abdominal Pain.

Musculoskeletal: Arthritis, Back pain, Joint pain, Muscle Weakness, Neck Pain/Stiffness.

Ear/Nose/Throat/Mouth: Congestion, Sinus Problems.

Genitourinary: Back Pain, Flank Pain, Nocturia.

Other than noted above, all other systems negative

Vital Signs:

11/16/2015: BP Systolic: 134, BP Diastolic: 76, Pulse: 70, Height: 61", Weight: 128 lbs, BMI: 24.183, BMI Plan: Yes

PHYSICAL EXAMINATION:

CONSTITUTIONAL:

General Appearance: Well developed, well nourished White female in no acute distress.

Eyes: pupils and irises - lens transparent, without opacities or scars, sclera - sclera not edematous, not injected, not icteric.

RESPIRATORY: Normal respiratory effort without labor. No wheezing.

ABDOMEN: The liver and spleen appear to be normal. Abdomen is **obese. Abdomen distended.** Abdominal scars are well-healed. No abdominal masses or tenderness noted.

GENTOURINARY:

Kidneys: No CVA tenderness area of left kidney. No CVA tenderness area of right kidney.

Urethral Meatus: The meatus appears to be normal in size. A 3 mm caruncle is noted. The meatus is atrophic.

Urethra: There is no urethral hypermobility. Q-tip test is negative.

Pelvic Examination:

POP-Q

Catheter Residual: 10 ml Urine clear

Measurements:

Aa: -3cm

Ba: -3cm

C: -5cm

gh: +4cm

pb: +3cm

tv: +7cm

Ap: 0cm

Bp: 0cm Uterus and cervix are surgically absent. Anus and perineum normal, with good sphincter tone.

External Genitalia: Atrophic external genitalia

Vagina: No cystocele present. A **grade 2 rectocele** is present. No splinting to empty bowels. She has a vaginal mesh EXTRUSION of the left proximal Prolift arm and cuff. A 5mm x 10mm area is exposed and friable; this bleeds easily. The lateral attachment into the pelvic side wall is tender (moderately) to palpation. There is less banding on the right, but it is also compatible with likely mesh contracture; no right sided banding has extruded.

She has significant atrophy around her introitus, especially posteriorly. There is no clear lichen sclerosis et atrophicus.

Nurse present for pelvic examination.

MUSCULOSKELETAL: Gait appears normal.

NEUROLOGICAL: Patient appears to be well oriented to time, place, and person.

LYMPHATICS: There are no abnormal nodes palpated in either inguinal area.

ASSESSMENT AND PLAN

Results received through this encounter (11/16/15)

None

Historical results

None

Vital Signs:

11/16/2015: BP Systolic: 134, BP Diastolic: 76, Pulse: 70, Height: 61", Weight: 128 lbs, BMI: 24.183, BMI Plan: Yes

Urinalysis Automated (81003-QW):

11/16/2015: Color: YELLOW, Clarity: CLR, Glucose: NEG, Bilirubin: NEG, Ketone: NEG, Specific Gravity: 1.020, Blood: NEG, pH: 7.0, Protein: NEG, Urobilinogen: 0.2, Nitrite: NEG, Leukocytes: NEG, Collection Method: Clean Catch

KROPF, DIANE (DOB: Feb 10, 1944)

Nov 16, 2015

page 4

PROBLEM LIST:

Dyspareunia (ICD9: 625.0, ICD10: N94.1): New With Added Workup

CURRENT IMPRESSION:

Erosion of implanted vaginal mesh and other prosthetic materials to surrounding organ or tissue, initial encounter (ICD9: 629.31, ICD10: T83.711A): New With Added Workup

Pelvic and perineal pain (ICD9: 625.9, ICD10: R10.2): New With Added Workup

Postmenopausal atrophic vaginitis (ICD9: 627.3, ICD10: N95.2): New With Added Workup

Rectocele (ICD9: 618.04, ICD10: N81.6): New With Added Workup

DISCUSSIONS:

Topical Estrogen Therapy Review:

Discussed at length the benefits and risks of topical estrogen therapy. I explained the relationship of any estrogen therapy with breast cancer. The decision to use or not use was a joint decision made by me and the patient with consideration to her health risks.

NEW PLAN OF TREATMENT:

Ordered

Lab - Urine Culture & Sensitivity - Ordered 11/16/15

Cath specimen

Schedule: Today

MU - Educational Material - Ordered 11/16/15

Disease Specific Pamphlet given to patient

MU - Patient Summary of Care Record Provided - Ordered 11/16/15

Completed by Provider

None

PATIENT SUMMARY: She has dyspareunia, vaginal and abdominal pain related to extrusion and contraction of Prolift vaginal mesh. We discussed the diagnosis and management options.

Vaginal pain and dyspareunia: I recommend excision of extruded mesh and tight mesh contractures of the proximal Prolift arms. This will improve vaginal wall mobility and hopefully allow her to have sex, again. However, the pain may persist and prolapse may recur. I also recommend that she comply with the topical estradiol therapy that was prescribed given her atrophy; improving the atrophy will help her heal better from any planned mesh revision.

For the rectocele: I explained that this is asymptomatic and needs no current therapy. However, add dietary fiber (20 grams a day), and avoid straining and constipation. No surgery is indicated for that at this time.

Discontinued Medications:

none

PRESCRIPTION THIS VISIT:

Date medications last reviewed with patient: 11/16/15

(The purpose of any medications prescribed on this visit, mode of administration, and side effects were discussed with the patient.)

INSTRUCTIONS/CODING DATA REVIEW:

Data:

I had an extensive counseling session with the patient concerning the diagnosis and treatment options.

I had an extensive discussion with the patient's family concerning the diagnosis and treatment.

I performed an extensive review and summary of the patient's medical records.

Patient Instructions:

Patient is instructed to call me at the office or contact my answering service if there is no improvement, or if the condition worsens.

CPT coding calculation based upon time.

(New Patient-Time)

60 or more minutes were spent face to face with this patient and/or her family. I spent greater than 50% of that time providing counseling and/or coordination of care. She and I discussed her diagnosis. I counseled her concerning **dyspareunia** and the various ways to manage the condition. I advised her of the prognosis concerning her options.

Electronically signed by: Ricardo R. Gonzalez, M.D. 11/17/2015 06:17:34 PM CST

Edited by: Erica Munoz 11/16/2015 11:27:21 AM CST

Edited by: Claudia Garcia 11/16/2015 11:35:56 AM CST

Encounter Notes

From User: 12claudiag

To User:

rgonzalez

Sent Date: 11/16/2015 11:32:14 AM CST

Patient:

KROPF, DIANE

Home Phone:

(540)846-2576

Work Phone:

(540)785-2706

Email:

JD2@COMCAST.NET

Priority:

Normal

Provider:

rgonzalez

Location:

1270-Powers

Notes:

Patient is in your office

Electronically Signed by: null 11/16/2015 11:32:14 AM CST